UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

for the quarterly period ended September 30, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

COMMISSION FILE NUMBER: 001-37590

AVALO THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**45-0705648**
(State of incorporation)	(I.R.S. Employer Identification No.)
540 Gaither Road, Suite 400 **Rockville, Maryland 20850**	**(410) 522-8707**
(Address of principal executive offices)	(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.001 par value	AVTX	Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☑	Smaller reporting company ☑
Emerging growth company ☐	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes☐ No ☑

As of November 7, 2023, the registrant had 192,382,419 shares of common stock outstanding.

AVALO THERAPEUTICS, INC.

FORM 10-Q

For the Quarter Ended September 30, 2023

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

AVALO THERAPEUTICS, INC. and SUBSIDIARIES

Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)

	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 10,180	$ 13,172
Other receivables	1,538	1,919
Inventory, net	—	20
Prepaid expenses and other current assets	940	1,290
Restricted cash, current portion	1	15
Total current assets	12,659	16,416
Property and equipment, net	2,071	2,411
Goodwill	14,409	14,409
Restricted cash, net of current portion	131	131
Total assets	$ 29,270	$ 33,367
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 789	$ 2,882
Deferred revenue	—	88
Accrued expenses and other current liabilities	5,216	13,214
Notes payable, current	—	5,930
Total current liabilities	6,005	22,114
Notes payable, non-current	—	13,486
Royalty obligation	2,000	2,000
Deferred tax liability, net	164	141
Derivative liability	4,950	4,830
Other long-term liabilities	1,456	1,711
Total liabilities	14,575	44,282
Stockholders' equity (deficit):		
Common stock—$0.001 par value; 200,000,000 shares authorized at September 30, 2023 and December 31, 2022;192,382,419 and 9,430,535 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	192	9
Additional paid-in capital	341,469	292,900
Accumulated deficit	(326,966)	(303,824)
Total stockholders' equity (deficit)	14,695	(10,915)
Total liabilities and stockholders' equity (deficit)	$ 29,270	$ 33,367

See accompanying notes to the unaudited condensed consolidated financial statements.

AVALO THERAPEUTICS, INC. and SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive (Loss) Income (Unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Product revenue, net	$ 236	$ 432	$ 1,353	$ 2,638
License revenue	—	14,517	—	14,517
Total revenues, net	236	14,949	1,353	17,155
Operating expenses:				
Cost of product sales	247	528	1,505	2,814
Research and development	1,249	7,042	11,917	25,136
Selling, general and administrative	2,490	3,284	7,624	17,752
Amortization expense	—	—	—	38
Total operating expenses	3,986	10,854	21,046	45,740
	(3,750)	4,095	(19,693)	(28,585)
Other expense:				
Interest expense, net	(1,553)	(898)	(3,498)	(3,221)
Change in fair value of derivative liability	100	—	(120)	—
Other expense, net	(17)	—	(42)	(20)
Total other expense, net	(1,470)	(898)	(3,660)	(3,241)
(Loss) income before taxes	(5,220)	3,197	(23,353)	(31,826)
Income tax expense	8	5	23	20
Net (loss) income and comprehensive loss	$ (5,228)	$ 3,192	$ (23,376)	$ (31,846)
Net (loss) income per share of common stock, basic and diluted	$ (0.11)	$ 0.34	$ (0.96)	$ (3.39)

See accompanying notes to the unaudited condensed consolidated financial statements.

AVALO THERAPEUTICS, INC. and SUBSIDIARIES

Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) (Unaudited)
(In thousands, except share amounts)

	Common stock		Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	capital	deficit	(deficit) equity
Three Months Ended September 30, 2023					
Balance, June 30, 2023	**14,036,940**	**$ 14**	**$ 314,755**	**$ (321,738)**	**$ (6,969)**
Issuance of common shares pursuant to ATM Program, net	177,013,776	177	25,762	—	25,939
Exercise of pre-funded warrants for common shares	1,331,703	1	(1)	—	—
Stock-based compensation	—	—	953	—	953
Net loss	—	—	—	(5,228)	(5,228)
Balance, September 30, 2023	**192,382,419**	**$ 192**	**$ 341,469**	**$ (326,966)**	**$ 14,695**

	Common stock		Additional paid-in	Accumulated	Total stockholders'
	Shares	Amount	capital	deficit	(deficit) equity
Nine Months Ended September 30, 2023					
Balance, December 31, 2022	**9,430,535**	**$ 9**	**$ 292,900**	**$ (303,824)**	**$ (10,915)**
Issuance of shares of common stock and warrants in underwritten public offering, net	3,770,000	4	13,744	—	13,748
Issuance of common shares pursuant to ATM Program, net	179,058,448	179	32,291	—	32,470
Retirement of common shares in exchange for pre-funded warrants	(1,300,000)	(1)	(3,873)	234	(3,640)
Issuance of pre-funded warrants in exchange for retirement of common shares	—	—	3,640	—	3,640
Exercise of pre-funded warrants for common shares	1,403,813	1	(1)	—	—
Shares purchased through employee stock purchase plan	19,623	—	67	—	67
Stock-based compensation	—	—	2,701	—	2,701
Net loss	—	—	—	(23,376)	(23,376)
Balance, September 30, 2023	**192,382,419**	**$ 192**	**$ 341,469**	**$ (326,966)**	**$ 14,695**

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount			
Three Months Ended September 30, 2022					
Balance, June 30, 2022	**9,405,724**	**$ 9**	**$ 291,244**	**$ (297,204)**	**$ (5,951)**
Impact of reverse stock split fractional share round-up	8,380	—	—	—	—
Stock-based compensation	—	—	731	—	731
Net loss	—	—	—	3,192	3,192
Balance, September 30, 2022	**9,414,104**	**$ 9**	**$ 291,975**	**$ (294,012)**	**$ (2,028)**

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' (deficit) equity
	Shares	Amount			
Nine Months Ended September 30, 2022					
Balance, December 31, 2021	**9,399,517**	**$ 9**	**$ 285,239**	**$ (262,166)**	**$ 23,082**
Restricted stock units vested during period	938	—	—	—	—
Shares purchased through employee stock purchase plan	5,269	—	25	—	25
Impact of reverse stock split fractional share round-up	8,380	—	—	—	—
Stock-based compensation	—	—	6,711	—	6,711
Net loss	—	—	—	(31,846)	(31,846)
Balance, September 30, 2022	**9,414,104**	**$ 9**	**$ 291,975**	**$ (294,012)**	**$ (2,028)**

See accompanying notes to the unaudited condensed consolidated financial statements.

AVALO THERAPEUTICS, INC. and SUBSIDIARIES

Condensed Consolidated Statements of Cash Flows (Unaudited)

(Amounts in thousands)

	Nine Months Ended September 30,	
	2023	**2022**
Operating activities		
Net loss	$ (23,376)	$ (31,846)
Adjustments to reconcile net loss used in operating activities:		
Depreciation and amortization	115	131
Stock-based compensation	2,701	6,711
Accretion of debt discount	1,828	1,040
Allowance for other long-term asset	—	1,000
Deferred taxes	23	20
Change in fair value of derivative liability	120	—
Changes in assets and liabilities:		
Accounts receivable, net	—	1,060
Other receivables	381	2,425
Inventory, net	20	16
Prepaid expenses and other assets	350	1,254
Lease incentive	158	—
Accounts payable	(2,094)	(1,922)
Deferred revenue	—	442
Accrued expenses and other liabilities	(8,088)	(3,144)
Lease liability, net	(52)	2
Net cash used in operating activities	(27,914)	(22,811)
Investing activities		
Leasehold improvements	(158)	—
Disposal of property and equipment	25	—
Purchase of property and equipment	—	(95)
Net cash used in investing activities	(133)	(95)
Financing activities		
Proceeds from sale of common stock pursuant to ATM Program, net	32,470	—
Proceeds from issuance of common stock and warrants in underwritten public offering, net	13,748	—
Principal payments on Notes	(21,244)	(14,806)
Proceeds from issuance of common stock under employee stock purchase plan	67	25
Net cash provided by (used in) financing activities	25,041	(14,781)
Decrease in cash, cash equivalents and restricted cash	(3,006)	(37,687)
Cash, cash equivalents, and restricted cash at beginning of period	13,318	54,864
Cash, cash equivalents, and restricted cash at end of period	$ 10,312	$ 17,177
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 1,925	$ 2,256
Supplemental disclosures of non-cash activities		
Fair value of common stock retired in exchange for issuance of prefunded warrants	$ 3,640	$ —

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same such amounts shown in the condensed consolidated statements of cash flows (in thousands):

	September 30,	
	2023	**2022**
Cash and cash equivalents	$ 10,180	$ 16,943
Restricted cash, current	1	53
Restricted cash, non-current	131	181
Total cash, cash equivalents and restricted cash	$ 10,312	17,177

See accompanying notes to the unaudited condensed consolidated financial statements.

AVALO THERAPEUTICS, INC. and SUBSIDIARIES

Notes to Unaudited Condensed Consolidated Financial Statements

1. Business

Avalo Therapeutics, Inc. (the "Company" or "Avalo" or "we") is a clinical stage biotechnology company focused on the treatment of immune dysregulation by developing therapies that target the LIGHT network.

LIGHT (Lymphotoxin-like, exhibits Inducible expression, and competes with HSV Glycoprotein D for Herpesvirus Entry Mediator ("HVEM"), a receptor expressed by T lymphocytes; also referred to as TNFSF14) is an immunoregulatory cytokine. LIGHT and its signaling receptors, HVEM (TNFRSF14), and lymphotoxin β receptor (TNFRSF3), form an immune regulatory network with two co-receptors of herpesvirus entry mediator, checkpoint inhibitor B and T Lymphocyte Attenuator ("BTLA"), and CD160 (collectively, the "LIGHT-signaling network" or the "LIGHT network"). Accumulating evidence points to the dysregulation of the LIGHT network as a disease-driving mechanism in autoimmune and inflammatory reactions in barrier organs. Therefore, we believe reducing LIGHT levels can moderate immune dysregulation in many acute and chronic inflammatory disorders.

Avalo was incorporated in Delaware and commenced operation in 2011 and completed its initial public offering in October 2015.

Liquidity

For the nine months ended September 30, 2023, Avalo generated a net loss of $23.4 million and negative cash flows from operations of $27.9 million. As of September 30, 2023, Avalo had $ 10.2 million in cash and cash equivalents. In the three months ended September 30, 2023, the Company raised approximately $25.9 million of net proceeds under its "at-the-market" (or "ATM") program. On September 22, 2023, the Company and its lenders entered into a Payoff Letter (the "Payoff Letter"), pursuant to which the Company repaid all outstanding principal, inclusive of the final payment fee, and interest under the Loan Agreement (as defined in Note 9) in the aggregate amount of $14.3 million. As a result of the payment, all obligations of the parties under the Loan Agreement were deemed satisfied and terminated.

The Company will require additional financing to fund its operations and to continue to execute its business strategy within one year after the date the unaudited condensed consolidated financial statements included herein were issued. To mitigate these conditions and to meet the Company's capital requirements, management plans to use its current cash on hand along with some combination of the following: (i) financings, (ii) out-licensing, strategic alliances/collaborations or sale of core and non-core programs, and (iii) mergers and acquisitions. There can be no assurance that any financing or business development initiatives can be realized by the Company, or if realized, what the terms may be, or that any amount that the Company is able to raise will be adequate. Raising capital would be more difficult if our common stock is delisted from Nasdaq. The Company is currently in the delisting hearings process with Nasdaq (for more information refer to the "Recent Developments" section under "Management's Discussion and Analysis of Financial Condition and Results of Operations"). Further, if the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, the Company might have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates. If the Company requires but is unable to obtain additional funding, the Company may be forced to make further reductions in spending, delay, suspend, reduce or eliminate some or all of its planned research and development programs, or liquidate assets where possible. Due to the uncertainty regarding future financing and other potential options to raise funds, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern within one year after the date that the financial statements in this Quarterly Report on Form 10-Q were issued.

The accompanying unaudited condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company's ability to continue as a going concern is dependent upon its ability to obtain additional capital as described above. The unaudited financial statements as of September 30, 2023 do not include any adjustments that might result from the outcome of this uncertainty.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The Company's unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly the Company's financial position, results of operations, and cash flows. The condensed consolidated balance sheet at December 31, 2022 has been derived from audited financial statements at that date. The interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to instructions, rules, and regulations prescribed by the United States Securities and Exchange Commission ("SEC").

The Company believes that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited condensed consolidated financial statements are read in conjunction with the December 31, 2022 audited consolidated financial statements.

Unless otherwise indicated, all amounts in the following tables are in thousands except share and per share amounts.

Accounting Pronouncements Adopted in 2023

In January 2017, the FASB issued ASU No. 2017-04 *Intangibles - Goodwill and Other Topics (Topic 350): Simplifying the Test for Goodwill Impairment.* This guidance eliminates the requirement to calculate the implied fair value of goodwill of a reporting unit to measure a goodwill impairment charge. Instead, a company will record an impairment charge based on the excess of a reporting unit's carrying amount over its fair value. This new standard was adopted effective January 1, 2023 and will be applied upon any recognition of any future goodwill impairment charge. This ASU has not had a material impact on our financial statements.

Significant Accounting Policies

During the nine months ended September 30, 2023, there were no significant changes to the Company's summary of significant accounting policies contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the SEC on March 29, 2023.

3. Revenue

Avalo generated its product revenue from sales of Millipred®, an oral prednisolone indicated across a wide variety of inflammatory conditions, which is considered a prescription drug. Avalo's license and supply agreement for Millipred® expired on September 30, 2023. The Company sold its prescription drug in the United States primarily through wholesale distributors. Wholesale distributors accounted for substantially all of the Company's net product revenues and trade receivables. For the three months ended September 30, 2023, the Company's two largest customers accounted for approximately 72% and 28% of the Company's total net product revenues. For the nine months ended September 30, 2023, the Company's two largest customers accounted for approximately 58% and 42% of the Company's total net product revenues. Net revenue from sales of prescription drugs was $0.2 million and $0.4 million for the three months ended September 30, 2023 and 2022, respectively, and $1.4 million and $2.6 million for the nine months ended September 30, 2023 and 2022, respectively.

The Company does not expect future gross revenue related to the Millipred® product given the product's license and supply agreement expired on September 30, 2023. However, the Company will continue to monitor estimates for commercial liabilities, such as sales returns. As additional information becomes available, the Company could recognize expense (or a benefit) for differences between actuals or updated estimates to the reserves previously recognized.

Pursuant the Millipred® license and supply agreement, Avalo was required to pay the supplier fifty percent of the net profit of the Millipred® product following each calendar quarter, subject to a $0.5 million quarterly minimum payment dependent on Avalo reaching certain net profit amounts as stipulated in the agreement. The profit share commenced on July 1, 2021 and ended on September 30, 2023. Within twenty-five months of September 30, 2023, the net profit share is subject to a reconciliation process where estimated deductions to arrive at net profit will be trued up to actuals and could result in Avalo owing additional amounts to Teva or vice versa.

Aytu BioScience, Inc. ("Aytu"), to which the Company sold its rights, title, and interests in assets relating to certain commercialized products in 2019 (the "Aytu Transaction"), managed Millipred® commercial operations until August 31, 2021 pursuant to transition service agreements, which included managing the third-party logistics provider. As a result, Aytu collected cash on behalf of Avalo for revenue generated by sales of Millipred® from the second quarter of 2020 through the third quarter of 2021. The transition services agreement allows Aytu to withhold up to $1.0 million until December of 2024. In the second quarter of 2022, Avalo fully reserved the $ 1.0 million receivable as a result of Aytu's conclusion within its Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 that substantial doubt existed with respect to its ability to continue as a going concern within one year after the date those financial statements were issued. As of September 30, 2023, the total receivable balance was approximately $0.9 million. The receivable remains fully reserved given Aytu's conclusion in its most recent publicly disclosed financial statements that substantial doubt exists with respect to its ability to continue as a going concern within one year after the date of financial statements were issued, which is prior to December of 2024. We will continue to re-assess its collectability each reporting period.

4. Net Loss Per Share

Basic and diluted EPS is provided below for common stock for the three and nine months ended September 30, 2023 and September 30, 2022.

EPS for common stock is computed by dividing the sum of distributed earnings and undistributed earnings by the weighted average number of shares outstanding for the period. The weighted average number of common shares outstanding as of September 30, 2023 and 2022 include the weighted average effect of pre-funded warrants, the exercise of which requires nominal consideration for the delivery of the shares of common stock.

Diluted net loss per share includes the potential dilutive effect of common stock equivalents as if such securities were converted or exercised during the period, when the effect is dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock units, which are included under the "treasury stock method" when dilutive; and (ii) common stock to be issued upon the exercise of outstanding warrants, which are included under the "treasury stock method" when dilutive. Because the impact of these items is generally anti-dilutive during periods of net loss, there is no difference between basic and diluted loss per common share for periods with net losses. In periods of net loss, losses are allocated to the participating security only if the security has not only the right to participate in earnings, but also a contractual obligation to share in the Company's losses.

The following tables set forth the computation of basic and diluted net (loss) income per share of common stock for the three and nine months ended September 30, 2023 and September 30, 2022 (in thousands, except share and per share amounts):

	Three Months Ended September 30,	
	2023	2022
Basic (loss) income per share:		
Net (loss) income	$ (5,228)	$ 3,192
Weighted average shares	46,764,117	9,413,466
Basic net (loss) income per share	$ (0.11)	$ 0.34
Diluted (loss) income per share:		
Net (loss) income	$ (5,228)	$ 3,192
Weighted average shares - basic	46,764,117	9,413,466
Effect of dilutive securities:		
Potentially dilutive shares	—	166
Weighted average shares - diluted	46,764,117	9,413,632
Diluted net (loss) income per share	$ (0.11)	$ 0.34

	Nine Months Ended September 30,	
	2023	2022
Basic and diluted loss per share:		
Net loss	$ (23,376)	$ (31,846)
Weighted average shares	24,281,306	9,404,679
Basic and diluted net loss per share	$ (0.96)	$ (3.39)

The following outstanding securities have been excluded from the computation of diluted weighted shares outstanding for the three and nine months ended September 30, 2023 and 2022, as they could have been anti-dilutive:

	Three and Nine Months Ended September 30,	
	2023	2022
Stock options	1,849,229	1,260,906
Warrants on common stock[1]	4,136,990	366,990
Restricted Stock Units	—	—

[1] *The weighted average number of common shares outstanding includes the weighted average outstanding pre-funded warrants for the period because their exercise price was nominal. There were no pre-funded warrants outstanding as of September 30, 2023.*

5. Fair Value Measurements

ASC No. 820, *Fair Value Measurements and Disclosures* ("ASC 820"), defines fair value as the price that would be received to sell an asset, or paid to transfer a liability, in the principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value standard also establishes a three-level hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The valuation hierarchy is based upon the transparency of inputs to the valuation of an asset or liability on the measurement date. The three levels are defined as follows:

- Level 1—inputs to the valuation methodology are quoted prices (unadjusted) for an identical asset or liability in an active market.
- Level 2—inputs to the valuation methodology include quoted prices for a similar asset or liability in an active market or model-derived valuations in which all significant inputs are observable for substantially the full term of the asset or liability.
- Level 3—inputs to the valuation methodology are unobservable and significant to the fair value measurement of the asset or liability.

The following table presents, for each of the fair value hierarchy levels required under ASC 820, the Company's assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	September 30, 2023 Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets			
Investments in money market funds*	$ 9,324	$ —	$ —
Liabilities			
Derivative liability	$ —	$ —	$ 4,950

	December 31, 2022 Fair Value Measurements Using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets			
Investments in money market funds*	$ 12,133	$ —	$ —
Liabilities			
Derivative liability	$ —	$ —	$ 4,830

**Investments in money market funds are reflected in cash and cash equivalents on the accompanying unaudited condensed consolidated balance sheets.*

As of September 30, 2023, the Company's financial instruments included cash and cash equivalents, restricted cash, accounts receivable, other receivables, prepaid and other current assets, accounts payable, accrued expenses and other current liabilities and derivative liability. As of December 31, 2022, the Company's financial instruments included cash and cash equivalents, restricted cash, accounts receivable, other receivables, prepaid and other current assets, accounts payable, accrued expenses and other current liabilities, derivative liability and debt.

The carrying amounts reported in the accompanying unaudited condensed consolidated financial statements for cash and cash equivalents, restricted cash, accounts receivable, other receivables, prepaid and other current assets, accounts payable, and accrued expenses and other current liabilities approximate their respective fair values because of the short-term nature of these accounts.

Level 3 Valuation

The table presented below is a summary of changes in the fair value of the Company's Level 3 valuation for the derivative liability for the nine months ended September 30, 2023:

	Derivative liability
Balance at December 31, 2022	$ 4,830
Change in fair value of derivative liability	120
Balance at September 30, 2023	$ 4,950

In the fourth quarter of 2022, Avalo sold its economic rights to future milestone and royalty payments for previously out-licensed assets AVTX-501, AVTX-007, and AVTX-611 to ES Therapeutics, LLC ("ES"), an affiliate of Armistice, in exchange for $5.0 million (the "ES Transaction"). At the time of the transaction, Armistice was a significant stockholder of the Company and whose chief investment officer, Steven Boyd, and managing director, Keith Maher, served on Avalo's Board until August 8, 2022. The ES Transaction was approved in accordance with Avalo's related party transaction policy.

The economic rights sold include (a) rights to a milestone payment of $20.0 million upon the filing and acceptance of an NDA for AVTX-501 pursuant to an agreement with Janssen Pharmaceutics, Inc., (the "AVTX-501 Milestone") and (b) rights to any future milestone payments and royalties relating to AVTX-007 under a license agreement with Apollo AP43 Limited, including up to $6.25 million of development milestones, up to $67.5 million in sales-based milestones, and royalty payments of a low single digit percentage of annual net sales (which percentage increases to another low single digit percentage if annual net sales exceed a specified threshold) (the "AVTX-007 Milestones and Royalties"). In addition, Avalo waived all its rights to AVTX-611 sales-based payments of up to $20.0 million that were payable by ES.

The exchange of the economic rights of the AVTX-501 Milestone and AVTX-007 Milestones and Royalties for cash meets the definition of a derivative instrument. The fair value of the derivative liability is determined using a combination of a scenario-based method and an option pricing method (implemented using a Monte Carlo simulation). The significant inputs including probabilities of success, expected timing, and forecasted sales as well as market-based inputs for volatility, risk-adjusted discount rates and allowance for counterparty credit risk are unobservable and based on the best information available to Avalo. Certain information used in the valuation is inherently limited in nature and could differ from Janssen and Apollo's internal estimates.

The fair value of the derivative liability as of the transaction date was approximately $4.8 million, of which $3.5 million was attributable to the AVTX-501 Milestone and $1.3 million was attributable to the AVX-007 Milestones and Royalties. Subsequent to the transaction date, at each reporting period, the derivative liability is remeasured at fair value. As of September 30, 2023, the fair value of the derivative liability was $5.0 million, of which $3.7 million was attributable to the AVTX-501 Milestone and $ 1.3 million was attributable to the AVTX-007 Milestones and Royalties. For the nine months ended September 30, 2023, the $0.1 million change in fair value was recognized in other expense, net in the accompanying unaudited condensed consolidated statements of operations and comprehensive (loss) income.

The fair value of the AVTX-501 Milestone was primarily driven by an approximate 23% probability of success to reach the milestone in approximately 4.1 years. The fair value of AVTX-007 Milestones and Royalties were primarily driven by an approximate 17% probability of success, time to commercialization of approximately 5.1 years, and sales forecasts with peak annual net sales reaching $300 million. As discussed above, these unobservable inputs were estimated by Avalo based on limited publicly available information and therefore could differ from Janssen and Apollo's internal development plans. Any changes to these inputs may result in significant changes to the fair value measurement. Notably, the probability of success is the largest driver of the fair value and therefore changes to such input would likely result in significant changes to such fair value.

In the event that Janssen and/or Apollo are required to make payment(s) to ES Therapeutics pursuant to the underlying agreements, Avalo will recognize revenue under its existing contracts with those customers for that amount when it is no longer probable there would be a significant revenue reversal with any differences between the fair value of the derivative liability related to that payment immediately prior to the revenue recognition and revenue recognized to be recorded as other expense. However, given Avalo is no longer entitled to collect these payments, the potential ultimate settlement of the payments in the future from Janssen and/or Apollo to ES Therapeutics (and the future mark-to-market activity each reporting period) will not impact Avalo's future cash flows.

No changes in valuation techniques or inputs occurred during the nine months ended September 30, 2023 and 2022. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the nine months ended September 30, 2023 and 2022.

6. Leases

Avalo currently occupies two leased properties, both of which serve as administrative office space. The Company determined that both of these leases are operating leases based on the lease classification test performed at lease commencement.

The annual base rent for the Company's office located in Rockville, Maryland is $0.2 million, subject to annual 2.5% increases over the term of the lease. The applicable lease provided for a rent abatement for a period of 12 months following the Company's date of occupancy. The lease has an initial term of 10 years from the date the Company made its first annual fixed rent payment, which occurred in January 2020. The Company has the option to extend the lease two times, each for a period of five years, and may terminate the lease as of the sixth anniversary of the first annual fixed rent payment, upon the payment of a termination fee.

The initial annual base rent for the Company's office located in Chesterbrook, Pennsylvania is $0.2 million and the annual operating expenses are approximately $0.1 million. The annual base rent is subject to periodic increases of approximately 2.4% over the term of the lease. The lease has an initial term of 5.25 years from the lease commencement on December 1, 2021.

The weighted average remaining term of the operating leases at September 30, 2023 was 4.8 years.

Supplemental balance sheet information related to the leased properties include (in thousands):

	As of	
	September 30, 2023	December 31, 2022
Property and equipment, net	$ 1,393	$ 1,750
Accrued expenses and other current liabilities	$ 536	$ 532
Other long-term liabilities	1,456	1,711
Total operating lease liabilities	$ 1,992	$ 2,243

The operating lease right-of-use (ROU) assets are included in property and equipment, net and the lease liabilities are included in accrued expenses and other current liabilities and other long-term liabilities in our unaudited condensed consolidated balance sheets. The Company utilized a weighted average discount rate of 9.1% to determine the present value of the lease payments.

The components of lease expense for the three and nine months ended September 30, 2023 and 2022 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating lease cost*	$ 97	$ 134	$ 350	$ 373

**Includes short-term leases, which are immaterial.*

The following table shows a maturity analysis of the operating lease liabilities as of September 30, 2023 (in thousands):

	Undiscounted Cash Flows
October 1, 2023 through December 31, 2023	$ 133
2024	537
2025	547
2026	557
2027	258
2028	201
Thereafter	224
Total lease payments	$ 2,457
Less implied interest	(465)
Total	$ 1,992

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of September 30, 2023 and December 31, 2022 consisted of the following (in thousands):

	As of	
	September 30, 2023	December 31, 2022
Research and development	$ 1,331	$ 6,293
Compensation and benefits	449	2,699
Selling, general and administrative	530	1,008
Commercial operations	2,156	1,694
Royalty payment	214	508
Lease liability, current	536	532
Other	—	480
Total accrued expenses and other current liabilities	$ 5,216	$ 13,214

8. Cost Reduction Plan

In the first quarter of 2022, the Board approved a cost reduction plan to enable the Company to execute its strategy of prioritizing the development of its most promising programs (the "Plan"). A reduction in workforce plan was approved to reduce headcount and related expenses. The reduction in workforce plan was considered a one-time termination benefit as defined by ASC No. 420, *Exit or Disposal Cost Obligations*. The one-time termination benefits mainly relate to severance payments to separated employees. As a result, the Company recognized $1.5 million of expense during the first quarter of 2022, of which $0.7 million was recognized in research and development expense, and $0.8 million was recognized in selling, general and administrative expense. $1.4 million of severance payments were paid in the year ended December 31, 2022 and the remaining $0.1 million was paid in the nine months ended September 30, 2023. Additionally, $0.4 million of stock-based compensation expense was recognized in the first quarter of 2022 related to the Plan, which was mainly related to accelerated vesting of certain separated employees' stock options.

In addition, previously and separately, during the first quarter of 2022, the Company separated certain section 16 executive officers. Each of the former executives are entitled to the benefits provided in their respective separation agreements, which include severance payments to be paid over twelve to eighteen months. As a result, the Company recognized $1.7 million expense during the first quarter of 2022 within selling, general and administrative expenses. Additionally, the Company accelerated the vesting of certain outstanding stock options and extended the exercisability periods, which resulted in $3.9 million of compensation cost recognized in first quarter of 2022. Refer to Note 11 for information regarding stock compensation expense related to separations entered into the first quarter of 2022.

9. Notes Payable

On June 4, 2021, the Company entered into a $35.0 million venture loan and security agreement (the "Loan Agreement") with Horizon Technology Finance Corporation ("Horizon") and Powerscourt Investments XXV, LP ("Powerscourt", and together with Horizon, the "Lenders"). Between June and September of 2021, the Company borrowed the full $35.0 million (the "Note") available under the Loan Agreement. In the second quarter of 2022, the Company, as collectively agreed upon with the Lenders, prepaid $15.0 million of principal and accrued interest. In June of 2023, the Company, as collectively agreed upon with the Lenders, prepaid $6.0 million of principal. On September 22, 2023, the Company and the Lenders entered into a Payoff Letter (the "Payoff Letter"), pursuant to which the Company repaid all outstanding principal, inclusive of the final payment fee, and interest under the Loan Agreement in the aggregate amount of $14.3 million. As a result of the payment, all obligations of the parties under the Loan Agreement were deemed satisfied and terminated.

On June 4, 2021, pursuant to the Loan Agreement, the Company issued warrants to the Lenders to purchase 33,656 shares of the Company's common stock with an exercise price of $31.20 per share (the "Warrants"). The Warrants are exercisable for ten years from the date of issuance. Pursuant to the Payoff Letter, Avalo's obligations under the Warrants shall survive pursuant to the original terms at issuance. The Warrants, which met equity classification, were recognized as a component of permanent stockholders' equity within additional paid-in-capital and were recorded at the issuance date using a relative fair value allocation method.

The Company recognized debt issuance costs and the amount allocated to the warrants as a debt discount on the date of issuance and amortized these costs to interest expense using the effective interest method over the original term of the loan. As a result of the payoff in the third quarter of 2023, the Company accelerated the remaining $0.9 million amortization of the debt discount, which was recognized as interest expense for the three and nine months ended September 30, 2023.

Balance sheet information related to the note payable for the Notes is as follows (in thousands):

	As of	
	September 30, 2023	December 31, 2022
Initial Note	$ —	$ 12,139
Second Note	—	6,070
Third Note	—	3,035
Notes payable, gross[1]	$ —	$ 21,244
Less: Unamortized debt discount and issuance costs	—	1,828
Carrying value of notes payable, current	$ —	$ 19,416
Less: Current portion	—	5,930
Carrying value of notes payable, non-current	$ —	$ 13,486

[1] *Balance as of December 31, 2022 includes $1.1 million final payment fee for the Notes, which represents 3% of the original principal loan amount.*

As of September 30, 2023, there were no remaining contractual future principal payments.

10. Capital Structure

Pursuant to the Company's amended and restated certificate of incorporation, the Company is authorized to issue two classes of stock, common stock and preferred stock. At September 30, 2023, the total number of shares of capital stock the Company was authorized to issue was 205,000,000, of which 200,000,000 was common stock and 5,000,000 was preferred stock. All shares of common and preferred stock have a par value of $0.001 per share.

Common Stock

At-the-Market Offering Program

On May 4, 2023, the Company entered into an "at-the-market" sales agreement (the "Sales Agreement") with Oppenheimer & Co. Inc. ("Oppenheimer"), pursuant to which the Company could sell from time to time, shares of its common stock having an aggregate offering price of up to $9,032,567 through Oppenheimer. In August 2023, the Company and Oppenheimer entered into an amendment to the sales agreement (the "Amended Sales Agreement") to increase the aggregate offering amount under the Sales Agreement to $ 50,000,000 inclusive of shares sold prior to the amendment. In the nine months ended September 30, 2023, the Company sold approximately 179.1 million shares under the ATM program for net proceeds of approximately $32.5 million.

Exchange Agreement

In May 2023, the Company entered into an exchange agreement (the "Exchange Agreement") with entities affiliated with Venrock Healthcare Capital Partners ("Venrock"), pursuant to which the Company exchanged an aggregate of 1.3 million shares of the Company's common stock, par value $0.001 per share, owned by Venrock for pre-funded warrants (the "Exchange Warrants") to purchase an aggregate of 1.3 million shares of common stock (subject to adjustment in the event of stock splits, recapitalization and other similar events affecting common stock), with an exercise price of $0.001 per share.

The Exchange Warrants were exercisable at any time, except that the Exchange Warrants would not be exercisable by Venrock if, upon giving effect or immediately prior thereto, Venrock would beneficially own more than 9.99% of the total number of issued and outstanding Avalo common stock, which percentage could change at the holders' election to any amount less than or equal to 19.99% upon 61 days' notice to the Company. Venrock exercised the Exchange Warrants in full in September of 2023.

In accordance with ASC No. 505*, Equity*, in the second quarter of 2023, the Company recorded the retirement of the common stock exchanged as a reduction of common shares outstanding and a corresponding impact to additional paid-in-capital and accumulated deficit at the fair value of the Exchange Warrants on the issuance date. The Exchange Warrants were classified as equity in accordance with ASC 480 and the fair value of the Exchange Warrants was recorded as a credit to additional paid-in-capital and is not subject to remeasurement. The Company determined that the fair value of the Exchange Warrants is substantially similar to the fair value of the retired shares on the issuance date due to the negligible exercise price for the Exchange Warrants.

Q1 2023 Financing

On February 7, 2023, the Company closed an underwritten public offering of3,770,000 shares of its common stock and warrants to purchase up to3,770,000 shares of common stock, at a combined price to the public of $3.98 per share and warrant, resulting in net proceeds of approximately $13.7 million, after deducting the underwriting discounts and commissions and offering expenses paid by us. The warrants were immediately exercisable at an exercise price of $5.00 per share and are exercisable forone year from the issuance date. Armistice, who was a significant stockholder of the Company at the time of the financing, participated in the offering by purchasing 0.5 million shares of common stock and0.5 million warrants, on the same terms as all other investors. Certain affiliates of Nantahala Capital Management LLC and Point72 Asset Management, L.P., which each beneficially owned greater than 5% of the Company's outstanding common stock at the time of the offering, participated in the offering on the same terms as all other investors.

The warrants were classified as a component of permanent stockholders' deficit within additional paid-in capital. The warrants are equity classified because they (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria. In addition, such warrants do not provide any guarantee of value or return.

Common Stock Warrants

At September 30, 2023, the following common stock warrants were outstanding:

Number of common shares underlying warrants	Exercise price per share	Expiration date
333,334	$ 150.00	June 2024
33,656	$ 31.20	June 2031
3,770,000	$ 5.00	February 2024
4,136,990		

11. Stock-Based Compensation

2016 Equity Incentive Plan

In April 2016, our board of directors adopted the 2016 Equity Incentive Plan, which was approved by our stockholders in May 2016 and which was subsequently amended and restated in May 2018 and August 2019 with the approval of our board of directors and our stockholders (the "2016 Third Amended Plan"). During the term of the 2016 Third Amended Plan, the share reserve will automatically increase on the first trading day in January of each calendar year ending on (and including) January 1, 2026, by an amount equal to 4% of the total number of outstanding shares of common stock of the Company on the last trading day in December of the prior calendar year. On January 1, 2023, pursuant to the terms of the 2016 Third Amended Plan, an additional 377,221 shares were made available for issuance. As of September 30, 2023, there were 51,284 shares available for future issuance under the 2016 Third Amended Plan.

Option grants expire after ten years. Employee options typically vest over four years. Employees typically receive a new hire option grant, as well as an annual grant in the first or second quarter of each year. In addition, in the first and fourth quarters of 2022 and second quarter of 2023, employees were also granted options that vest on the first anniversary of the grant date. Options granted to directors typically vest either immediately or over a period of one or three years. Directors may elect to receive stock options in lieu of board compensation, which vest immediately. For stock options granted to employees and non-employee directors, the estimated grant date fair market value of the Company's stock-based awards is amortized ratably over the individuals' service periods, which is the period in which the awards vest. Stock-based compensation expense includes expense related to stock options and employee stock purchase plan shares. The amount of stock-based compensation expense recognized for the three and nine months ended September 30, 2023 and 2022 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 371	$ 279	$ 1,028	$ 931
Selling, general and administrative	582	452	1,673	5,780
Total stock-based compensation	$ 953	$ 731	$ 2,701	$ 6,711

As a result of separation agreements that the Company entered into in the first quarter of 2022 and in accordance with the terms of the pre-existing employment agreements, the Company accelerated the vesting of certain separated employees' stock options and modified certain awards to extend the exercisability periods. The Company recognized $4.3 million of compensation cost in the first quarter of 2022, all of which was recognized in selling, general and administrative expense.

Stock options with service-based vesting conditions

The Company has granted options that contain service-based vesting conditions. The compensation cost for these options is recognized on a straight-line basis over the vesting periodsA summary of option activity for the nine months ended September 30, 2023 is as follows:

	Options Outstanding			
	Number of shares	Weighted average exercise price per share	Weighted average grant date fair value per share	Weighted average remaining contractual term (in years)
Balance at December 31, 2022	1,345,532	$ 28.24	$ 17.48	6.7
Granted	760,272	$ 2.72	$ 2.06	
Forfeited	(10,101)	$ 4.92	$ 3.56	
Expired	(339,910)	$ 42.99	$ 27.13	
Balance at September 30, 2023	1,755,793	$ 14.47	$ 9.01	8.4
Exercisable at September 30, 2023	595,159	$ 31.35	$ 18.43	6.9

In February 2023, the Company granted 0.3 million options with service-based vesting conditions to its employees as part of its annual stock option award that vest overfour years. In May 2023, the Company granted 0.3 million options with service-based vesting conditions to its employees that vest overone year.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. As of September 30, 2023, the aggregate intrinsic value of options outstanding was zero. There were 0.3 million options that vested during the nine months ended September 30, 2023 with a weighted average exercise price of $12.78 per share. The total grant date fair value of shares which vested during the nine months ended September 30, 2023 was $2.2 million.

The Company recognized stock-based compensation expense of $0.9 million and $2.6 million related to stock options with service-based vesting conditions for the three and nine months ended September 30, 2023, respectively. At September 30, 2023, there was $3.6 million of total unrecognized compensation cost related to unvested service-based vesting condition awards. The unrecognized compensation cost is expected to be recognized over a weighted-average period of 1.5 years.

Stock-based compensation assumptions

The following table shows the assumptions used to compute stock-based compensation expense for stock options with service-based vesting conditions granted under the Black-Scholes valuation model for the nine months ended September 30, 2023:

Service-based options	
Expected term of option (in years)	5 - 6.25
Expected stock price volatility	89.8% - 146.0%
Risk-free interest rate	3.43% - 4.13%
Expected annual dividend yield	0%

Stock options with market-based vesting conditions

As of September 30, 2023, there were 0.1 million exercisable stock options that contained market-based vesting conditions (that had been previously satisfied). The options have a weighted average share price per share of $39.53 and a weighted average remaining contractual term of 0.7 years. There were no stock options with market-based vesting conditions granted, exercised, or forfeited for the nine months ended September 30, 2023.

Employee Stock Purchase Plan

On April 5, 2016, the Company's board of directors approved the 2016 Employee Stock Purchase Plan (the "ESPP"). The ESPP was approved by the Company's stockholders and became effective on May 18, 2016 (the "ESPP Effective Date").

Under the ESPP, eligible employees can purchase common stock through accumulated payroll deductions at such times as are established by the administrator. The ESPP is administered by the compensation committee of the Company's board of directors. Under the ESPP, eligible employees may purchase stock at 85% of the lower of the fair market value of a share of the Company's common stock (i) on the first day of an offering period or (ii) on the purchase date. Eligible employees may contribute up to 15% of their earnings during the offering period. The Company's board of directors may establish a maximum number of shares of the Company's common stock that may be purchased by any participant, or all participants in the aggregate, during each offering or offering period. Under the ESPP, a participant may not accrue rights to purchase more than $25,000 of the fair market value of the Company's common stock for each calendar year in which such right is outstanding.

The Company initially reserved and authorized up to 41,667 shares of common stock for issuance under the ESPP. On January 1 of each calendar year, the aggregate number of shares that may be issued under the ESPP automatically increases by a number equal to the lesser of (i) 1% of the total number of shares of the Company's capital stock outstanding on December 31 of the preceding calendar year, (ii) 41,667 shares of the Company's common stock, or (iii) a number of shares of the Company's common stock as determined by the Company's board of directors or compensation committee. The number of shares were increased by 41,667 on January 1, 2023. As of September 30, 2023,192,079 shares remained available for issuance.

In accordance with the guidance in ASC 718-50, *Employee Share Purchase Plans*, the ability to purchase shares of the Company's common stock at the lower of the offering date price or the purchase date price represents an option and, therefore, the ESPP is a compensatory plan under this guidance. Accordingly, stock-based compensation expense is determined based on the option's grant-date fair value and is recognized over the requisite service period of the option. The Company used the Black-Scholes valuation model and recognized stock-based compensation expense of $48 thousand and $0.1 million for the three and nine months ended September 30, 2023, respectively.

12. Income Taxes

The Company recognized minimal income tax expense for the three and nine months ended September 30, 2023 and 2022 due to the significant valuation allowance against the Company's deferred tax assets and the current and prior period losses.

13. Commitments and Contingencies

Litigation

Litigation - General

The Company may become party to various contractual disputes, litigation, and potential claims arising in the ordinary course of business. Reserves are established in connection with such matters when a loss is probable and the amount of such loss can be reasonably estimated. The Company currently does not believe that the resolution of such matters will have a material adverse effect on its financial position or results of operations except as otherwise disclosed in this report.

Dispute Notice

On August 14, 2023, the Company received a notice from Apollo AP43 Limited alleging that the Company is in breach of the License Agreement between them dated July 29, 2022 by virtue of owing $837,522 to a service provider under the terms of that license. The notice formally initiates a dispute resolution process under the license, beginning with further negotiations between the companies' executive officers. The possible loss to the Company is between $0 and $837,522. The Company does not believe a loss is currently probable and therefore has not recognized a contingent liability as of September 30, 2023.

Possible Future Milestone Payments for In-Licensed Compounds

General

Avalo is a party to license and development agreements with various third parties, which contain future payment obligations such as royalties and milestone payments. The Company recognizes a liability (and related expense) for each milestone if and when such milestone is probable and can be reasonably estimated. As typical in the biotechnology industry, each milestone has unique risks that the Company evaluates when determining the probability of achieving each milestone and the probability of success evolves over time as the programs progress and additional information is obtained. The Company considers numerous factors when evaluating whether a given milestone is probable including (but not limited to) the regulatory pathway, development plan, ability to dedicate sufficient funding to reach a given milestone and the probability of success.

AVTX-002 KKC License Agreement

On March 25, 2021, the Company entered into a license agreement with Kyowa Kirin Co., Ltd. ("KKC") for exclusive worldwide rights to develop, manufacture and commercialize AVTX-002, KKC's first-in-class fully human anti-LIGHT (TNFSF14) monoclonal antibody for all indications (the "KKC License Agreement"). The KKC License Agreement replaced the Amended and Restated Clinical Development and Option Agreement between the Company and KKC dated May 28, 2020.

Under the KKC License Agreement, the Company paid KKC an upfront license fee of $10.0 million, which we recognized within research and development expenses in 2021. The Company is also required to pay KKC up to an aggregate of $112.5 million based on the achievement of specified development and regulatory milestones. Upon commercialization, the Company is required to pay KKC sales-based milestones aggregating up to $75.0 million tied to the achievement of annual net sales targets.

Additionally, the Company is required to pay KKC royalties during a country-by-country royalty term equal to a mid-teen percentage of annual net sales. The Company is required to pay KKC a double-digit percentage (less than 30%) of the payments that the Company receives from any sublicensing of its rights under the KKC License Agreement, subject to certain exclusions. Avalo is responsible for the development and commercialization of AVTX-002 in all indications worldwide (other than the option in the KKC License Agreement that, upon exercise by KKC, allows KKC to develop, manufacture and commercialize AVTX-002 in Japan). In addition to the KKC License Agreement, Avalo is subject to additional royalties upon commercialization of up to an amount of less than 10% of net sales.

No expense related to the KKC License Agreement was recognized in the nine months ended September 30, 2023. There has beemo cumulative expense recognized as of September 30, 2023 related to the milestones under this license agreement. The Company will continue to monitor the milestones at each reporting period.

AVTX-006 Astellas License Agreement

The Company has an exclusive license agreement with OSI Pharmaceuticals, LLC, an indirect wholly owned subsidiary of Astellas Pharma, Inc. ("Astellas"), for the worldwide development and commercialization of the novel, second generation mTORC1/2 inhibitor (AVTX-006). Under the terms of the license agreement, there was an upfront license fee of $0.5 million. The Company is required to pay Astellas up to an aggregate of $5.5 million based on the achievement of specified development and regulatory milestones. The Company is also required to pay Astellas a tiered mid-to-high single digit percentage of the payments that Avalo receives from any sublicensing of its rights under the Astellas license agreement, subject to certain exclusions. Upon commercialization, the Company is required to pay Astellas royalties during a country-by-country royalty term equal to a tiered mid-to-high single digit percentage of annual net sales. Avalo is fully responsible for the development and commercialization of the program.

No expense related to this license agreement was recognized in the nine months ended September 30, 2023.There has been $0.5 million of cumulative expense recognized as of September 30, 2023 related to the milestones under this license agreement, which was recognized in 2021. The Company will continue to monitor the remaining milestones at each reporting period.

AVTX-008 Sanford Burnham Prebys License Agreement

On June 22, 2021, the Company entered into an Exclusive Patent License Agreement with Sanford Burnham Prebys Medical Discovery Institute (the "Sanford Burnham Prebys License Agreement") under which the Company obtained an exclusive license to a portfolio of issued patents and patent applications covering an immune checkpoint program (AVTX-008).

Under the terms of the Sanford Burnham Prebys License Agreement, the Company incurred an upfront license fee of $0.4 million, as well as patent costs of $0.5 million, which we recognized within research and development expenses and within selling, general and administrative expenses, respectively, in 2021. The Company is required to pay Sanford Burnham Prebys up to an aggregate of $24.2 million based on achievement of specified development and regulatory milestones. Upon commercialization, the Company is required to pay Sanford Burnham Prebys sales-based milestone payments aggregating up to $50.0 million tied to annual net sales targets. Additionally, the Company is required to pay Sanford Burnham Prebys royalties during a country-by-country royalty term equal to a low-to-mid single digit percentage of annual net sales. The Company is also required to pay Sanford Burnham Prebys a tiered low-double digit percentage of the payments that Avalo receives from sublicensing of its rights under the Sanford Burnham Prebys License Agreement, subject to certain exclusions. Avalo is fully responsible for the development and commercialization of the program.

No material expense related to the Sanford Burnham Prebys License Agreement was recognized in the nine months ended September 30, 2023. There has beemo cumulative expense recognized as of September 30, 2023 related to the milestones under this license agreement. The Company will continue to monitor the milestones at each reporting period.

Possible Future Milestone Proceeds for Out-Licensed Compounds

AVTX-301 Out-License

On May 28, 2021, the Company out-licensed its rights in respect of its non-core asset, AVTX-301, to Alto Neuroscience, Inc. ("Alto"). The Company initially in-licensed the compound from an affiliate of Merck & Co., Inc. in 2013.

Under the out-license agreement, the Company received a mid-six digit upfront payment from Alto, which we recognized as license revenue in 2021. The Company is also eligible to receive up to an aggregate of $18.6 million based on the achievement of specified development, regulatory and commercial sales milestones. Additionally, the Company is entitled to a less than single digit percentage royalty based on annual net sales. Alto is fully responsible for the development and commercialization of the program.

The Company has not recognized any milestones as of September 30, 2023.

AVTX-406 License Assignment

On June 9, 2021, the Company assigned its rights, title, interest, and obligations under an in-license covering its non-core asset, AVTX-406, to ES, a wholly owned subsidiary of Armistice, who was a significant stockholder of the Company at the time of the financing and whose chief investment officer, Steven Boyd, and managing director, Keith Maher, served on Avalo's Board until August 8, 2022. The transaction with ES was approved in accordance with Avalo's related party transaction policy.

Under the assignment agreement, the Company received a low-six digit upfront payment from ES, which we recognized as license revenue in 2021. The Company is also eligible to receive up to an aggregate of $6.0 million based on the achievement of specified development and regulatory milestones. Upon commercialization, the Company is eligible to receive sales-based milestone payments aggregating up to $20.0 million tied to annual net sales targets. ES is fully responsible for the development and commercialization of the program.

The Company has not recognized any milestones as of September 30, 2023.

Acquisition Related and Other Contingent Liabilities

Aevi Merger Possible Future Milestone Payments

In the first quarter of 2020, the Company consummated its merger with Aevi Genomic Medicine Inc. ("Aevi"), in which Avalo acquired the rights to AVTX-002, AVTX-006 and AVTX-007 (the "Merger" or the "Aevi Merger"). A portion of the consideration for the Aevi Merger included two future contingent development milestones worth up to an additional $6.5 million, payable in either shares of Avalo's common stock or cash, at the election of Avalo.

The first milestone was the enrollment of a patient in a Phase 2 study related to AVTX-002 (for treatment of pediatric onset Crohn's disease), AVTX-006 (for treatment of any indication) or AVTX-007 (for treatment of any indication) prior to February 3, 2022, which would have resulted in a milestone payment of $2.0 million. The Company did not meet the first milestone prior to February 3, 2022. Therefore, no contingent consideration related to this milestone was recognized as of September 30, 2023 andno future contingent consideration will be recognized.

The second milestone is the receipt of an NDA approval for either AVTX-006 or AVTX-007 from the FDA on or prior to February 3, 2025. If this milestone is met, the Company is required to make a milestone payment of $4.5 million. The contingent consideration related to the second development milestone will be recognized if and when such milestone is probable and can be reasonably estimated. No contingent consideration related to the second development milestone has been recognized as of September 30, 2023. The Company will continue to monitor the second milestone at each reporting period.

Ichorion Asset Acquisition Possible Future Milestone Payments

In September 2018, the Company acquired Ichorion Therapeutics, Inc., including acquiring three compounds for inherited metabolic disorders known as CDGs (AVTX-801, AVTX-802 and AVTX-803) and one other preclinical compound. Consideration for the transaction included shares of Avalo common stock and three future contingent development milestones for the acquired compounds worth up to an additional $15.0 million. All milestones are payable in either shares of the Company's common stock or cash, at the election of Avalo.

The first and second milestones were marketing approval of the first and second product, respectively, by the FDA on or prior to December 31, 2021, which would have resulted in milestone payments of $6.0 million and $5.0 million, respectively. The Company did not meet the first or second milestone as of December 31, 2021. As a result, no contingent consideration related to these milestones was recognized as of September 30, 2023 and no future contingent consideration will be recognized.

The third milestone is marketing approval of a protide molecule by the FDA on or prior to December 31, 2023. If this milestone is met, the Company is required to make a milestone payment of $4.0 million. The contingent consideration related to the third development milestone will be recognized if and when such milestone is probable and can be reasonably estimated No contingent consideration related to the third milestone has been recognized as of September 30, 2023. The Company will continue to monitor the third development milestone at each reporting period.

On October 27, 2023, the Company divested AVTX-801, AVTX-802 and AVTX-803 (see Note 14). Avalo remains responsible for the future milestone payment related to the protide molecule described above.

AVTX-006 Royalty Agreement with Certain Related Parties

In July 2019, Aevi entered into a royalty agreement, and liabilities thereunder were assumed by Avalo upon close of the Aevi Merger in February 2020. The royalty agreement provided certain investors, including LeoGroup Private Investment Access, LLC on behalf of Garry Neil, the Company's Chief Executive Officer and Chairman of the Board, and Mike Cola, the Company's former Chief Executive Officer (collectively, the "Investors"), a royalty stream, in exchange for a one-time aggregate payment of $2.0 million (the "Royalty Agreement"). Pursuant to the Royalty Agreement, the Investors will be entitled collectively to an aggregate amount equal to a low-single digit percentage of the aggregate net sales of the Company's second generation mTORC1/2 inhibitor, AVTX-006. At any time beginning three years after the date of the first public launch of AVTX-006, Avalo may exercise, at its sole discretion, a buyout option that terminates any further obligations under the Royalty Agreement in exchange for a payment to the Investors of an aggregate of 75% of the net present value of the royalty payments. A majority of the independent members of the board of directors and the audit committee of Aevi approved the Royalty Agreement.

Avalo assumed this Royalty Agreement upon closing of the Aevi Merger and it is recorded as a royalty obligation within the Company's accompanying unaudited condensed consolidated balance sheet as of September 30, 2023 and December 31, 2022. Because there is a significant related party relationship between the Company and the Investors, the Company has treated its obligation to make royalty payments under the Royalty Agreement as an implicit obligation to repay the funds advanced by the Investors. As the Company makes royalty payments in accordance with the Royalty Agreement, it will reduce the liability balance. At the time that such royalty payments become probable and estimable, and if such amounts exceed the liability balance, the Company will impute interest accordingly on a prospective basis based on such estimates, which will result in a corresponding increase in the liability balance.

Karbinal Royalty Make-Whole Provision

In 2018, in connection with the acquisition of certain commercialized products, the Company entered into a supply and distribution agreement (the "Karbinal Agreement") with TRIS Pharma Inc. ("TRIS"). As part of the Karbinal Agreement, the Company had an annual minimum sales commitment, which is based on a commercial year that spans from August 1 through July 31, of 70,000 units through 2025. The Company was required to pay TRIS a royalty make whole payment ("Make-Whole Payments") of $30 for each unit under the 70,000 units annual minimum sales commitment through 2025.

As a part of the Aytu transaction, the Company assigned all its payment obligations, including the Make-Whole Payments, under the Karbinal Agreement (collectively, the "TRIS Obligations") to Aytu. However, under the original license agreement, the Company could ultimately be liable for the TRIS Obligations to the extent Aytu fails to make the required payments. The future Make-Whole Payments to be made by Aytu are unknown as the amount owed to TRIS is dependent on the number of units sold.

14. Subsequent Events

On October 27, 2023, the Company closed the transaction under the asset purchase agreement (the "Purchase Agreement") to sell its rights, title and interest in, assets relating to AVTX-801, AVTX-802 and AVTX-803 (collectively, the "800 Series") to AUG Therapeutics, LLC ("AUG"). The Purchase Agreement was entered into in on September 11, 2023.

AUG paid an upfront payment of $150,000, as well as, for each compound, make a contingent milestone payment of $15,000,000 (for a potential aggregate of $45.0 million) if the first FDA approval is for an indication other than a Rare Pediatric Disease (as defined in the Purchase Agreement), or up to 20% of certain payments, if any, granted to AUG upon any sale of any priority review voucher granted to AUG by the FDA, net of any selling costs. Additionally, AUG assumed up to $ 150,000 of certain liabilities incurred prior to the date of the Purchase Agreement and assume all costs relating to the 800 Series from the date of the Purchase Agreement. Avalo will evaluate the accounting impact of the transaction in the fourth quarter of 2023.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements can be identified by the use of forward-looking words such as "projects," "may," "might," "will," "could," "would," "should," "continue," "seeks," "aims," "predicts," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," "pro forma" or other similar words (including their use in the negative), or by discussions of future matters such as: the future financial and operational outlook; the development of product candidates; and other statements that are not historical. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those below and elsewhere in this Quarterly Report on Form 10-Q, particularly in Part II – Item 1A, "Risk Factors," as well as in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 29, 2023, and in our other filings with the SEC. Statements made herein are as of the date of the filing of this Quarterly Report on Form 10-Q with the SEC and should not be relied upon as of any subsequent date. Unless otherwise required by applicable law, we do not undertake, and we specifically disclaim any obligation to update any forward-looking statements to reflect occurrences, developments, unanticipated events or circumstances after the date of such statement.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited financial statements and related notes that appear in Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes for the year ended December 31, 2022 appearing in our Annual Report on Form 10-K filed with the SEC on March 29, 2023.

Overview

Avalo Therapeutics, Inc. (the "Company" or "Avalo" or "we") is a clinical stage biotechnology company focused on the treatment of immune dysregulation by developing therapies that target the LIGHT network.

LIGHT (**L**ymphotoxin-like, exhibits **I**nducible expression, and competes with HSV **G**lycoprotein D for **H**erpesvirus Entry Mediator ("HVEM"), a receptor expressed by **T** lymphocytes; also referred to as TNFSF14) is an immunoregulatory cytokine. LIGHT and its signaling receptors, HVEM (TNFRSF14), and lymphotoxin β receptor (TNFRSF3), form an immune regulatory network with two co-receptors of herpesvirus entry mediator, checkpoint inhibitor B and T Lymphocyte Attenuator ("BTLA"), and CD160 (collectively, the "LIGHT-signaling network" or the "LIGHT network"). Accumulating evidence points to the dysregulation of the LIGHT-signaling network as a disease-driving mechanism in autoimmune and inflammatory reactions in barrier organs. Therefore, we believe reducing LIGHT levels can moderate immune dysregulation in many acute and chronic inflammatory disorders.

Management's primary evaluation of the success of the Company is the ability to progress its pipeline assets forward towards commercialization or opportunistically out-licensing rights to indications or geographies. This success depends not only on the operational execution of the programs, but also the ability to secure sufficient funding to support the programs. The Company is pursuing funding for its programs, including financings and out-licensing, strategic alliances/collaborations or sale of its core and non-core programs, as well as evaluating new opportunities to further argument its immunology pipeline.

Pipeline Summary

Quisovalimab (AVTX-002): Anti-LIGHT monoclonal antibody ("mAb") targeting immune-inflammatory diseases.

- Quisovalimab has shown a rapid and sustained reduction of LIGHT levels, as well as a favorable safety and tolerability profile, in all indications studied including COVID-19 acute respiratory distress syndrome ("ARDS"), Crohn's Disease and non-eosinophilic asthma ("NEA").

- Quisovalimab was statistically significant in reducing respiratory failure and mortality in patients hospitalized with COVID-19 ARDS in a randomized placebo-controlled trial. Quisovalimab also demonstrated positive trends in an open-label study in Crohn's Disease.

- A post-hoc analysis of the PEAK Trial showed a sub-population of NEA patients with baseline LIGHT levels over 125 pg/mL, which represented over 50% of patients, had an approximate 50% reduction in asthma-related events ("AREs") for patients treated with quisovalimab compared to placebo.

- Avalo is pursuing funding for the program and is considering a randomized placebo-controlled trial in patients with ulcerative colitis or other inflammatory conditions.

AVTX-008: BTLA agonist fusion protein targeting immune dysregulation disorders.

- AVTX-008 is uniquely positioned as a fusion protein with high-binding affinity and serum stability. It utilizes the natural ligand thus it may avoid the potential problems with agonist mAbs.

- Avalo previously identified a lead molecule, is evaluating several immune dysregulation disorders to pursue and plans to rapidly progress the asset to IND, subject to funding.

Recent Developments

The Company raised approximately $25.9 million of net proceeds under its "at-the-market" (or "ATM") program in the third quarter of 2023. Further, in September of 2023, the Company announced that it paid off the remainder of its debt in the aggregate amount of $14.3 million and as a result all payments and obligations under that debt were deemed satisfied and terminated.

On October 27, 2023, the Company divested its rights, title and interest in, assets relating to AVTX-801, AVTX-802 and AVTX-803 to AUG Therapeutics, LLC for an upfront payment of $150,000 and contingent milestone payments of up to an aggregate of $45.0 million.

As previously reported on Form 8-K filed on August 8, 2023, on August 8, 2023, Nasdaq Stock Market LLC ("Nasdaq") notified the Company that for the last 30 consecutive business days, the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule") and that for the last 30 consecutive business days, the Company's minimum Market Value of Listed Securities ("MVLS") was below the minimum of $35 million required for continued inclusion on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(2) (the "MVLS Rule"). Therefore, in accordance with Listing Rules 5810(c)(3)(A) and 5810(c)(3)(C), the Company was provided 180 calendar days, or until February 5, 2024, to regain compliance with both the Bid Price Rule and the MVLS Rule. Also as previously reported on Form 8-K filed on September 13, 2023, on September 12, 2023, the Company received notice from Nasdaq as of September 11, 2023, the Company's securities had a closing bid price of $0.10 or less for ten consecutive trading days triggering application of Listing Rule 5810(c)(3)(A)(iii) which states in part: if during any compliance period specified in Rule 5810(c)(3)(A), a company's security has a closing bid price of $0.10 or less for ten consecutive trading days, the Listing Qualifications Department shall issue a Staff Delisting Determination under Rule 5810 with respect to that security. As a result, the Staff determined to delist the Company's securities from Nasdaq, unless the Company timely requests an appeal of the Staff's determination to a Hearings Panel (the "Panel"). The Company timely requested an appeal of the Staff's determination to the Panel and the hearing took place on November 2, 2023. The Panel will issue a written decision, generally within 30 days of the hearing, that will determine whether the shares of the Company's common stock will remain listed on Nasdaq. The Company will timely report the decision of the Panel on Form 8-K upon receiving the written decision.

Liquidity

For the nine months ended September 30, 2023, Avalo generated a net loss of $23.4 million and negative cash flows from operations of $27.9 million. As of September 30, 2023, Avalo had $10.2 million in cash and cash equivalents. In the three months ended September 30, 2023, the Company raised approximately $25.9 million of net proceeds under its "at-the-market" (or "ATM") program. On September 22, 2023, the Company and its lenders entered into a Payoff Letter (the "Payoff Letter"), pursuant to which the Company repaid all outstanding principal, inclusive of the final payment fee, and interest under the Loan Agreement (as defined in Note 9 of the unaudited condensed consolidated financial statements) in the aggregate amount of $14.3 million. As a result of the payment, all obligations of the parties under the Loan Agreement were deemed satisfied and terminated.

The Company will require additional financing to fund its operations and to continue to execute its business strategy within one year after the date the unaudited condensed consolidated financial statements included herein were issued. To mitigate these conditions and to meet the Company's capital requirements, management plans to use its current cash on hand along with some combination of the following: (i) financings, (ii) out-licensing, strategic alliances/collaborations or sale of core and non-core programs, and (iii) mergers and acquisitions. There can be no assurance that any financing or business development initiatives can be realized by the Company, or if realized, what the terms may be, or that any amount that the Company is able to raise will be adequate. Raising capital would be more difficult if our common stock is delisted from Nasdaq. The Company is currently in the delisting hearings process with Nasdaq (for more information refer to the "Recent Developments" section above). Further, if the Company raises additional funds through collaborations, strategic alliances or licensing arrangements with third parties, the Company might have to relinquish valuable rights to its technologies, future revenue streams, research programs or product candidates. If the Company requires but is unable to obtain additional funding, the Company may be forced to make further reductions in spending, delay, suspend, reduce or eliminate some or all of its planned research and development programs, or liquidate assets where possible. Due to the uncertainty regarding future financing and other potential options to raise funds, management has concluded that substantial doubt exists with respect to the Company's ability to continue as a going concern within one year after the date that the financial statements in this Quarterly Report on Form 10-Q were issued.

The accompanying unaudited condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company's ability to continue as a going concern is dependent upon its ability to obtain additional capital as described above. The unaudited financial statements as of September 30, 2023 do not include any adjustments that might result from the outcome of this uncertainty.

Our Strategy

Our strategy for increasing stockholder value includes:

- Advancing our pipeline of compounds through development and to regulatory approval;
- Developing the go-to-market strategy to quickly and effectively market, launch, and distribute each of our compounds that receive regulatory approval;
- Opportunistically out-licensing rights to indications or geographies; and
- Acquiring or licensing rights to targeted, complementary differentiated preclinical and clinical stage compounds.

As noted above under "Liquidity", we need to raise money in the near term in order to continue as a going concern and be able to execute on this strategy.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

Product Revenue, Net

Net product revenue was $0.2 million for the three months ended September 30, 2023, compared to $0.4 million for the three months ended September 30, 2022. The decrease was mainly attributable to a decrease in units sold.

Avalo's license and supply agreement for its only commercial pharmaceutical product, Millipred®, which we consider non-core, expired on September 30, 2023. Therefore, we do not expect gross product revenue going forward. However, the Company will continue to monitor estimates for commercial liabilities, such as sales returns. As additional information becomes available, the Company could recognize expense (or a benefit) for differences between actuals or updated estimates to the reserves previously recognized.

Cost of Product Sales

Cost of product sales were $0.2 million for the three months ended September 30, 2023, compared to $0.5 million for the same period in 2022. The decrease was mainly attributable to a decrease in units sold, as discussed above.

Avalo's license and supply agreement for Millipred® expired on September 30, 2023. Therefore, we do not expect material cost of product sales going forward.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,	
	2023	2022
Preclinical expenses	$ 269	$ 479
Clinical expenses	915	3,003
CMC expenses	(1,191)	1,687
Internal expenses:		
Salaries, benefits and related costs	826	1,533
Stock-based compensation expense	371	279
Other	59	61
	$ 1,249	$ 7,042

Research and development expenses decreased $5.8 million for the three months ended September 30, 2023. This decrease was mainly driven by a $2.9 million decrease in chemistry, manufacturing, and controls ("CMC") expenses and $2.1 million decrease in clinical expenses. CMC expenses decreased due to the timing of manufacturing runs. Further, in the second quarter of 2023, the Company canceled its next manufacturing run for AVTX-002 and as a result incurred a cancelation fee of approximately $1.0 million. In the third quarter of 2023, the Company and manufacurer agreed to a reduced cancelation fee, which resulted in a reversal of the expense. Clinical expenses decreased due to decreased activities as a result of the AVTX-002 PEAK trial concluding in June of 2023. Additionally, salaries, benefits and related costs decreased $0.7 million primarily due to reduced headcount and reduced salary related costs.

Future research and development expenses are difficult to predict given they are highly dependent on the Company's ability to obtain additional capital to fund its programs and operations, including but not limited to financings and/or out-licensing, strategic alliance/collaborations or sale of its core and non-core programs.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the three months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,	
	2023	2022
Salaries, benefits and related costs	$ 582	$ 839
Legal, consulting and other professional expenses	1,146	1,687
Stock-based compensation expense	582	452
Advertising and marketing expense	7	6
Other	173	300
	$ 2,490	$ 3,284

Selling, general and administrative expenses decreased $0.8 million for the three months ended September 30, 2023 compared to the prior period. The decrease was driven by the impact of cost savings initiatives across legal, consulting and other professional expenses and salaries, benefits, as well as reduced headcount and reduced salary related costs. The decrease was partially offset by increased stock-based compensation expense during the period related to the options granted to employees in the second half of 2022 and first half of 2023.

Future selling, general and administrative expenses are difficult to predict given they are highly dependent on the Company's ability to obtain additional capital to fund its programs and operations, including but not limited to financings and/or out-licensing, strategic alliance/collaborations or sale of its core and non-core programs.

Other Expense, Net

The following table summarizes our other expense, net for the three months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,	
	2023	2022
Interest expense, net	(1,553)	(898)
Change in fair value of derivative liability	100	—
Other expense, net	(17)	—
	$ (1,470)	$ (898)

Other expense, net was mainly comprised of interest expense related to the Loan Agreement for the three months ended September 30, 2023 and 2022. On September 22, 2023, the Company and its lenders entered into a Payoff Letter, pursuant to which the Company repaid all outstanding principal, inclusive of the final payment fee, and interest under the Loan Agreement.

Interest expense, net increased $0.6 million mainly due to the acceleration of the remaining $0.9 million amortization of the debt discount recognized as a result of the Company's payoff of the debt in September of 2023. Prior to the payoff, the Company incurred lower interest expense as compared to the prior period due to a lower principal balance from previous prepayments.

As a result of the full payoff of the loan, we do not expect to recognize interest expense in the fourth quarter of 2023 or beyond.

Income Tax Expense

The Company recognized minimal income tax expense for both the three months ended September 30, 2023 and 2022.

Comparison of the Nine Months Ended September 30, 2023 and 2022

Product Revenue, Net

Net product revenue was $1.4 million for the nine months ended September 30, 2023, compared to $2.6 million for the nine months ended September 30, 2022. The decrease was mainly attributable to a decrease in units sold.

Avalo's license and supply agreement for our only commercial pharmaceutical product, Millipred®, which we consider non-core, expired on September 30, 2023. Therefore, we do not expect product revenue going forward. However, the Company will continue to monitor estimates for commercial liabilities, such as sales returns. As additional information becomes available, the Company could recognize expense (or a benefit) for differences between actuals or updated estimates to the reserves previously recognized.

Cost of Product Sales

Cost of product sales were $1.5 million for the nine months ended September 30, 2023, compared to $2.8 million for the same period in 2022. The decrease was mainly attributable to a decrease in units sold, as discussed above, paired with the $1.0 million reserve of the receivable due from Aytu in December 2024 that was recognized in cost of product sales for the nine months ended September 30, 2022.

Avalo's license and supply agreement for Millipred® expired on September 30, 2023. Therefore, we do not expect material cost of product sales going forward.

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Preclinical expenses	$ 844	$ 2,047
Clinical expenses	5,388	9,037
CMC expenses	1,787	6,800
Internal expenses:		
Salaries, benefits and related costs	2,699	6,093
Stock-based compensation expense	1,028	931
Other	171	228
	$ 11,917	$ 25,136

Research and development expenses decreased $13.2 million for the nine months ended September 30, 2023 as compared to the prior period. Notably, CMC and clinical expenses decreased $5.0 million and $3.6 million, respectively, as a result of reduced manufacturing and clinical trial activities for AVTX-002 driven by timing of study completion in June of 2023, paired with decreased expenses as a result of the out-license of AVTX-007 in July of 2022 and decreased spend on non-core programs in 2023.

Additionally, salaries, benefits and related costs decreased $3.4 million due to severance expense recognized in the first quarter of 2022 from headcount reductions that did not repeat, paired with lower salary costs in 2023 driven by the reduced headcount.

Future research and development expenses are difficult to predict given they are highly dependent on the Company's ability to obtain additional capital to fund its programs and operations, including but not limited to financings and/or out-licensing, strategic alliance/collaborations or sale of its core and non-core programs.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Salaries, benefits and related costs	$ 1,768	$ 5,435
Legal, consulting and other professional expenses	3,399	5,484
Stock-based compensation expense	1,673	5,780
Advertising and marketing expense	26	64
Other	758	989
	$ 7,624	$ 17,752

Selling, general and administrative expenses decreased $10.1 million for the nine months ended September 30, 2023 due to severance and stock-based compensation recognized in the first quarter of 2022 from headcount reductions, paired with decreased headcount and cost savings initiatives realized in 2023. Notably, we recognized $4.3 million of stock-based compensation in the first half of 2022 as a result of the acceleration and modification of certain separated employees' stock options that did not repeat. Additionally, salaries, benefits and related costs decreased $3.7 million due to $2.4 million of severance expense recognized in the first half of 2022 from headcount reductions that did not repeat, paired with lower salary costs in the first half of 2023 driven by the reduced headcount. Legal, consulting and other professional expenses decreased $2.1 million due to cost savings initiatives.

Future selling, general and administrative expenses are difficult to predict given they are highly dependent on the Company's ability to obtain additional capital to fund its programs and operations, including but not limited to financings and/or out-licensing, strategic alliance/collaborations or sale of its core and non-core programs.

Amortization Expense

The following table summarizes our amortization expense for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Amortization of intangible assets	$ —	$ 38

The acquired assembled workforce was fully amortized in the first quarter of 2022, thus driving the decrease as compared to the prior period.

Other Expense, Net

The following table summarizes our other expense, net for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Interest expense, net	(3,498)	(3,221)
Change in fair value of derivative liability	(120)	—
Other expense, net	(42)	(20)
	$ (3,660)	$ (3,241)

Other expense, net was mainly comprised of interest expense related to the Loan Agreement for the nine months ended September 30, 2023 and 2022. On September 22, 2023, the Company and its lenders entered into a Payoff Letter, pursuant to which the Company repaid all outstanding principal, inclusive of the final payment fee, and interest under the Loan Agreement.

Interest expense, net increased $0.3 million mainly due to the acceleration of the remaining $0.9 million amortization of the debt discount recognized as a result of the Company's payoff of the debt in September of 2023. This increase was partially offset by lower interest expense incurred prior to the final payoff due to a lower principal balance from previous prepayments.

As a result of the full payoff of the loan, we do not expect to recognize interest expense in the fourth quarter of 2023 or beyond.

Income Tax Expense

The Company recognized minimal income tax expense for both the nine months ended September 30, 2023 and 2022.

Liquidity and Capital Resources

Uses of Liquidity

The Company uses cash to primarily fund the ongoing development of its research and development pipeline assets and costs associated with its organizational infrastructure. Future operating cash flows are difficult to predict given they are highly dependent on the Company's ability to obtain additional capital to fund its programs and operations, including but not limited to financings and/or out-licensing, strategic alliance/collaborations or sale of its core and non-core programs.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	$ (27,914)	$ (22,811)
Investing activities	(133)	(95)
Financing activities	25,041	(14,781)
Net decrease in cash and cash equivalents	$ (3,006)	$ (37,687)

Net cash used in operating activities

Net cash used in operating activities was $27.9 million for the nine months ended September 30, 2023 and consisted primarily of a net loss of $23.4 million and non-cash adjustments to reconcile net loss to net cash used in operating activities including stock-based compensation of $2.7 million and accretion of the debt discount of $1.8 million. Accrued expenses and other current liabilities and accounts payable decreased $8.1 million and $2.1 million, respectively, from December 31, 2022.

Net cash used in operating activities was $22.8 million for the nine months ended September 30, 2022, and consisted primarily of a net loss of $31.8 million and non-cash adjustments to reconcile net loss to net cash used in operating activities including stock-based compensation of $6.7 million and the full $1.0 million reserve on the Aytu receivable due December 2024.

Future operating cash flows are difficult to predict given they are highly dependent on the Company's ability to obtain additional capital to fund its programs and operations, including but not limited to financings and/or out-licensing, strategic alliance/collaborations or sale of its core and non-core programs.

Net cash used in investing activities

Net cash used in investing activities was minimal for the nine months ended September 30, 2023 and nine months ended September 30, 2022.

Net cash provided by (used in) financing activities

Net cash provided by financing activities for the nine months ended September 30, 2023 consisted of net proceeds of $32.5 million from the sale of common stock pursuant to the Company's at-the-market program and net proceeds of $13.7 million from an underwritten public offering that closed in February 2023, partially offset by debt principal payments of $21.2 million. In September of 2023, the Company repaid all outstanding principal, inclusive of the final payment fee, and interest under its loan agreement and therefore we do not expect any future principal payment outflows.

Critical Accounting Policies, Estimates, and Assumptions

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, which have been prepared in accordance with GAAP. In preparing the financial statements in conformity with GAAP, the Company makes estimates and assumptions that have an impact on assets, liabilities, revenue and expenses reported. These estimates can also affect supplemental information disclosed by us, including information about contingencies, risk, and financial condition. In our unaudited condensed consolidated financial statements, estimates are used for, but not limited to, revenue recognition, cost of product sales, stock-based compensation, fair value measurements, the valuation of derivative liabilities, cash flows used in management's going concern assessment, income taxes, goodwill, and clinical trial accruals. The Company believes, given current facts and circumstances, that our estimates and assumptions are reasonable, adhere to GAAP and are consistently applied. Inherent in the nature of an estimate or assumption is the fact that actual results may differ from estimates, and estimates may vary as new facts and circumstances arise. Our most critical accounting estimates and assumptions are included in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 29, 2023. There have been no material changes to our critical accounting policies during the nine months ended September 30, 2023.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by applicable SEC rules and regulations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) and Rule 15d-15(b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q of the effectiveness of the design and operation of our disclosure controls and procedures. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of the end of the period covered by this Quarterly Report on Form 10-Q.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the period covered by this Quarterly Report on Form 10-Q that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

The information set forth in Note 13, Commitments and Contingencies, under the heading "Litigation" to our Unaudited Condensed Financial Statements, included in Part I, Item 1 of this Quarterly Report on Form 10-Q, is incorporated herein by reference.

Item 1A. Risk Factors.

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 29, 2023 (the "2022 10-K"), as updated by our Quarterly Report on Form 10-Q filed with the SEC on August 3, 2023 (the "2023 Q2 10-Q"), which could materially affect our business, financial condition, or future results. The risks described in this Quarterly Report on 10-Q and the 2022 10-K and 2023 Q2 10-Q are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, or future results of operations and the trading price of our common stock.

Except for such additional information and the updated risk factor set forth below, we believe there have been no other material changes in our risk factors from those disclosed in our 2022 10-K and 2023 Q2 10-Q.

Risks Related to Our Financial Position and Capital Needs

The Company has a limited number of unissued and unreserved shares available for future issuance, which might impair its ability to conduct future financing and other transactions.

The Company's amended and restated certificate of incorporation, as amended, currently authorizes the Company to issue up to 200,000,000 shares of common stock and 5,000,000 shares of preferred stock. As of November 7, 2023, there was a total of 7,617,581 shares of common stock that were authorized but unissued, and the Company has currently reserved a significant number of these shares for future issuance pursuant to its outstanding warrants, equity awards and equity plans. As a result, the Company's ability to issue shares of common stock other than pursuant to existing arrangements will be limited until such time, if ever, that it is able to amend its amended and restated certificate of incorporation, as amended, to increase the amount of authorized but unissued shares of common stock. As described in the Company's definitive proxy statement filed with the SEC on October 19, 2023, the Company is presenting a proposal for stockholder vote at the annual meeting of stockholders to be held on December 5, 2023 to approve an amendment to its amended and restated certificate of incorporation, as amended, to effect a reverse stock split of its common stock at a ratio of between 1-for-5 and 1-for-250 as determined by its board. This proposal would provide the Company sufficient flexibility in regards to having enough shares of common stock available for future needs. There is no guarantee that this proposal will be approved by the Company's stockholders.

If the Company is unable to effect a reverse stock split, its ability to complete equity-based financings or other transactions that involve the potential issuance of its common stock or securities convertible or exercisable into its common stock, will be limited. In lieu of issuing common stock or securities convertible into the Company's common stock in any future equity financing transactions, the Company might need to issue some or all of our authorized but unissued shares of preferred stock, which would likely have superior rights, preferences and privileges to those of its common stock. If the Company is unable to issue additional shares of common stock or securities convertible or exercisable into its common stock, its ability to enter into strategic transactions such as acquisitions of companies or intellectual property, might also be limited. If the Company is unable to complete financing, strategic or other transactions due to its inability to issue additional shares of common stock or securities convertible or exercisable into its common stock, the Company's financial condition and business prospects may be materially harmed.

Item 6. Exhibits.

Exhibit Number	Description of Exhibit
1.1	Amendment No. 1 to the Sales Agreement, dated as of August 7, 2023, between Avalo Therapeutics, Inc. and Oppenheimer & Co. Inc. (incorporated by reference to Exhibit 1.1 to the Form 8-K filed on August 7, 2023.
2.1*#	Purchase Agreement, dated September 11, 2023, by and between AUG Therapeutics, LLC and Avalo Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Form 8-K filed on September 12, 2023).
3.1	Fourth Amended and Restated Bylaws of Avalo Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on October 17, 2023).
10.1	Second Forbearance Agreement, dated as of August 14, 2023, between Avalo Therapeutics, Inc. and Horizon Credit II LLC, Horizon Funding Trust 2019-1, Horizon Funding I, LLC, Powerscourt Investments XXV Trust, and Horizon Technology Finance Corporation (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on August 14, 2023).
10.2	Third Forbearance Agreement, dated as of September 13, 2023, between Avalo Therapeutics, Inc. and Horizon Credit II LLC, Horizon Funding Trust 2019-1, Horizon Funding I, LLC, Powerscourt Investments XXV Trust, and Horizon Technology Finance Corporation (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on September 13, 2023).
10.3	First Amendment to Loan Agreement, dated as of September 13, 2023, between Avalo Therapeutics, Inc. and Horizon Credit II LLC, Horizon Funding Trust 2019-1, Horizon Funding I, LLC, Powerscourt Investments XXV Trust, and Horizon Technology Finance Corporation (incorporated by reference to Exhibit 10.2 to the Form 8-K filed on September 13, 2023).
10.4	Payoff Letter, dated as of September 22, 2023, between Avalo Therapeutics, Inc. and Horizon Credit II LLC, Horizon Funding Trust 2019-1, Horizon Funding I, LLC, Powerscourt Investments XXV Trust, and Horizon Technology Finance Corporation (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on September 26, 2023).
31.1+	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+†	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Condensed Consolidated Balance Sheets as of September 30, 2023 (Unaudited) and December 31, 2022; (ii) Condensed Consolidated Statements of Operations (Unaudited) for the Three and Nine Months Ended September 30, 2023 and 2022; (iii) Condensed Consolidated Statements of Cash Flows (Unaudited) for the Nine Months Ended September 30, 2023 and 2022; (iv) Condensed Consolidated Statements of Changes in Stockholders' (Deficit) Equity (Unaudited) for the Three and Nine Months Ended September 30, 2023 and 2022; and (v) Notes to Unaudited Financial Statements.
104	Cover Page Interactive Data File, formatted in XBRL (included in Exhibit 101).

*Certain exhibits and schedules to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplemental copies of any of the omitted exhibits or schedules upon request by the U.S. Securities and Exchange Commission.

Certain confidential portions to this exhibit have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish copies of the unredacted exhibit to the SEC upon request.

+ Filed herewith.

† This certification is being furnished solely to accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Avalo Therapeutics, Inc.

Date: November 9, 2023

/s/ Christopher Sullivan

Christopher Sullivan
Chief Financial Officer
(on behalf of the registrant and as the registrant's principal financial officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Garry Neil, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Avalo Therapeutics, Inc. (the "registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023

/s/ Garry Neil, M.D.

Garry Neil, M.D.
Chief Executive Officer
(Registrant's Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Christopher Sullivan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Avalo Therapeutics, Inc. (the "registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023

/s/ Christopher Sullivan

Christopher Sullivan
Chief Financial Officer
(Registrant's Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Avalo Therapeutics, Inc. (the "Registrant") on Form 10-Q for the period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Garry Neil, Chief Executive Officer (principal executive officer) of the Registrant, and I, Christopher Sullivan, Chief Financial Officer (principal financial officer) of the Registrant, each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition at the end of the period covered by the Report and the results of operations of the Registrant for the periods covered by the Report.

Date: November 9, 2023	By:	/s/ Garry Neil, M.D.
	Name:	**Garry Neil, M.D.**
	Title:	**Chief Executive Officer** **(Registrant's Principal Executive Officer)**
Date: November 9, 2023	By:	/s/ Christopher Sullivan
	Name:	**Christopher Sullivan**
	Title:	**Chief Financial Officer** **(Registrant's Principal Financial Officer)**

The foregoing certifications are not deemed filed with the Securities and Exchange Commission for purposes of section 18 of the Securities Exchange Act of 1934, as amended (Exchange Act), and are not to be incorporated by reference into any filing of Cerecor Inc. under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.